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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CLOW, LORI A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/21/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/479,608

Applicant(s)

DRMANAC ET AL.

Examiner

Lori A. Clow, Ph.D.

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 36-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's election without traverse of Group I, claims 1-35 in Paper No. 8 is acknowledged.

Drawings

Applicant is hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". Due to the above notification Applicant is required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Specification

The substitute specification filed 08/02/01 has not been entered because it does not conform to 37 CFR 1.125(b) because: a marked-up copy of the substitute specification has not been supplied.

Claims Rejections-35 USC 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103 that form the basis for the rejections under this section made in this Office action:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfenito (US 6,355,419). Alfenito teaches methods for preparing nucleic acid pools useful in hybridization studies and an improved method of identifying a nucleic acid and/or its representation in a sample (see abstract). Specifically, Alfenito teaches all of the limitations included in the instant claims 1-35.

With regards to claim 1 and 2 in the instant application, Alfenito discloses a method for detecting a target nucleic acid species including providing an array of probes affixed to a substrate and a plurality of labeled probes (pools) wherein each labeled probe is selected to have

Art Unit: 1631

a first nucleic acid sequence which is complementary to a first portion of a target nucleic acid and wherein the nucleic acid sequence of at least one probe affixed to the substrate is complementary to a second portion of the nucleic acid sequence of the target, the second portion being adjacent to the first portion, meeting the limitations of step a in claims 1 and 2; applying a target nucleic acid to the array under suitable conditions for hybridization of probe sequences to complementary sequences [.....], meeting the limitations of step b from claims 1 and 2. Other preferred aspects, which meet the limitations of step c from claims 1 and 2 include that at least two of the probes used will define overlapping sequences of the target nucleic acid (column 2, lines 17-29 and 39-40). Specifically a list of probes may be assembled wherein each probe is a perfect match to the nucleic acid to be sequenced. The probes are analyzed such that they are ordered in terms of maximal overlap. This is done by comparing a first probe to each of the other probes to determine which probe has a 3' end which has the longest sequence of bases at the 5' end of the second probe. Then the first and second probes may be overlapped and the process repeated (column 13, lines 22-34). Other specific embodiments which meet the limitations of the present of claims 1 and 2 include the teaching of target conformation using negative or positive probes, in order to eliminate false positive probes (column 3, lines 53-58; column 10, lines 35-56).

Alfenito teaches the limitations of claim 3 and 4 in column 28, example 9, which discloses hybridization assessment by using hybridization scores, which are analyzed as to degrees of hybridization by normalizing raw signals from fluorescent labels. Differences in amount of target are corrected for by dividing signals of each probe by an average signal for all probes. Then, signals may be scaled to compare data from different experiments (column 28 and

Art Unit: 1631

29, lines 61-67 and 1-2, respectively). Methods of analysis are done via an image analysis program, such as DOTS and scaled and evaluated statistically, for example, by the SCORES program (column 39, lines 19-22).

Alfenito also teaches the additional limitations of claim 5, 6, and 7 in column 3, lines 53-58, column 34, lines 17-26, and column 38, lines 54-59, for example.

Furthermore, the nucleic acids or fragments thereof may be applied to a first set of probes, before, after, or simultaneously with the second set of probes (column 12, lines 32-57) and, as described above, hybridization scores are assigned to each probe, thus meeting the limitations of claims 8-11. Either target or probe may be labeled with a fluorophore and the label can be attached to the terminal end or and internal nucleotide (as in claims 12-16) (see column 1, lines 46-48, lines 52-55, and lines 61-64). The probes may be arrayed or the nucleic acids may be arrayed so that they are addressed specifically and pooled on solid supports (column 1, lines 41-67).

Alfenito teaches the further limitations of claims 20-23, which embody covalently joining hybridized immobilized probes. Probes that bind to adjacent sites on the target are bound together and fragments that are not immobilized to the surface by chemical bonding to a member of the first set of probes are washed away during the assay. The bound probes from the second set may then be detected using appropriate means of labeling (fluorescence, chemiluminescence etc..) (column 12, lines 46-61).

Lastly, the limitations of claims 24-35 are also met as already described above. Whereas Alfenito does teach all of the limitations of the instant application the exact, step-by-step methods in the order in which they appear are not apparent. However, it would have been

Art Unit: 1631

obvious to one having ordinary skill in the art at the time the invention was made to modify the taught methods in such a way as to practice the steps in the order of the instant application.

Alfenito suggests that, upon consideration of the disclosure, one of skill in the art would appreciate that many other embodiments and variations could be made in the scope of the invention (column 18, lines 1-7). Thus, making it obvious to use the various techniques and methods of the invention in such a way as to produce an exact combination of desired elements. No claim is allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10 A.M. to 6 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Bill Phillips, whose telephone number is (703) 305-3419, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Application/Control Number: 09/479,608

Page 7

Art Unit: 1631

May 20, 2002

Lori A. Clow, Ph.D.

Art Unit 1631

Lori A. Clow



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